

Amendments to the Claims

The listing of claims will replace all prior versions, and listings, of claims in the application:

CLAIMS:

Claim 1 (Currently amended): A process for the purification of olanzapine characterized in that said process comprises the following steps:

- a) mixing olanzapine with an organic acid in an organic solvent or a mixture of organic solvents to form an olanzapine acid addition salt,
- b) precipitating and isolating the olanzapine acid addition salt and,
- c) transformation of the olanzapine acid addition salt to ~~olanzapine~~ olanzapine.

Claim 2 (Original): The process according to claim 1 wherein the organic acid in step (a) is selected from the group consisting of sulfonic acids or carboxylic acid.

Claim 3 (Original): The process according to claim 2 wherein the carboxylic acid is selected from the group consisting of fumaric acid and benzoic acid.

Claim 4 (Currently amended): The process according to claim 1 wherein the organic solvent in step (a) is selected from the group consisting of tetrahydrofuran tetrahydrofuran, acetone, dimethylformamide and acetonitrile.

Claim 5 (Currently amended): The process according to claim 1 wherein the mixture of organic solvents in step (a) is a mixture of tetrahydrofuran tetrahydrofuran with at least one polar solvent.

Claim 6 (Original): The process according to claim 5 wherein said polar solvent is selected from the group consisting of dimethylformamide, dimethylacetamide, N-methylpyrrolidone, 1,3-dimethyl-3,4,5,6-tetrahydro-2(1H)-pyrimidinone, 1,3 -imethyl-2-imidazolidinone, tetramethylurea, dimethyl sulfoxide, sulfolane, acetone and acetonitrile.

Claim 7 (Original): The process according to claim 1 characterized in that step (c) comprises the following substeps:

- i) dissolving an acid addition salt of olanzapine in water,
- ii) adjusting pH of the obtained solution to about 8-10,
- iii) extracting olanzapine from the water phase to the organic solvent phase and
- iv) isolating the acid addition salt of olanzapine from the organic solvent phase by concentrating the solution and separation of the crystals.

Claims 8-21 (Cancelled)

Claim 22 (Original): A process for the preparation of olanzapine in the form of an acid addition salt characterized in that said process comprises the following steps:

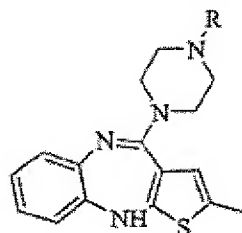
- a) 4-amino-2-methyl-10H-thieno[2,3-b][1,5]benzodiazepine hydrochloride is reacted with N-methylpiperazine to yield olanzapine and
- b) the obtained olanzapine is transformed to an acid addition salt thereof.

Claim 23 (Original): The process according to claim 22 characterized in that step (b) comprises the following substeps:

- i) the obtained reaction mixture is diluted with water,
- ii) the diluted reaction mixture is extracted with an organic solvent,
- iii) the organic phase is evaporated and the residue is diluted with a second solvent to obtain a solution,
- iv) an organic acid is added to the solution to precipitate olanzapine acid addition salt and
- v) precipitated olanzapine acid addition salt is isolated by separation of crystals.

Claim 24 (Original): A process for the preparation of olanzapine in the form of an acid addition salt characterized in that said process comprises the following steps:

- a) N-desmethyloanzapine is reacted with a methylating agent to yield olanzapine,
- b) the obtained reaction mixture is diluted with water and acidified with an acid,
- c) to the reaction mixture, an organic solvent is added and the phases are separated,
- d) the obtained water phase is neutralized and olanzapine is extracted with an organic solvent to obtain the organic solvent phase and
- e) an organic acid or substituted organic acid or an organic acid derivative of formula RX; wherein R represents an organic radical such as acetyl, propionyl, chloroacetyl and X is selected from a group of Cl, Br or I; or an organic acid anhydride; is added to the organic phase to form a N substituted N-desmethyloanzopine derivative of formula 2



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- f) the obtained organic solvent phase is optionally evaporated and the residue is diluted with a second organic solvent,
- g) an organic acid is added either to the obtained diluted solution or directly to the olanzapine extract from said extraction in step (d) and
- h) precipitated olanzapine acid addition salt is isolated by separation of the crystals.

Claim 25 (Original): The process according to claim 24 wherein the organic solvent in steps (c) and (d) is a chlorinated solvent.

Claim 26 (Original): The process according to claim 25 wherein said chlorinated solvent is methylene chloride.

Claim 27 (Original): The process according to claim 24 wherein the organic solvent in steps (c) and (d) is methylene chloride and said second solvent in step (f) is methanol.

Claims 28-34 (Cancelled)

Claim 35 (Currently amended): Olanzapine prepared according to ~~any of the previous~~ the processes disclosed in ~~the claims 1-7 and 29-33~~ claim 1 characterized in that N-desmethylolanzapine content in the final product of olanzapine is less than 0.1 %.

Claim 36 (Currently amended): Olanzapine prepared according to ~~any of the previous~~ the processes disclosed in ~~the claims 1-7, 16-18 and 29-33~~ claim 1 that contains less than 0.05 % of piperazine 1,4-bis-4-yl-(2-methyl)-10H-thieno-[2,3-b][1,5]benzodiazepine.

Claims 37-43 (Cancelled)